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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,016	02/09/2001	Patrick J. Muraca	5568/1020	6417
29932	7590	05/04/2004	EXAMINER	
PALMER & DODGE, LLP PAULA CAMPBELL EVANS 111 HUNTINGTON AVENUE BOSTON, MA 02199			MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/781,016

Applicant(s)

MURACA, PATRICK J.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-75 is/are pending in the application.
- 4a) Of the above claim(s) 47-50 and 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-46 and 51-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 6-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
~~Paper No./Mail Date~~ (2 sheets)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election of Group I (claims 6-46 and 51-74) in the Paper filed 10/6/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

INFORMATION DISCLOSURE STATEMENTS

The PTO Form 1449, filed 6/18/02, has been considered and is enclosed but the search report citation is lined through due to lacking a date of publication. A PTO Form 1449, filed 5/15/01, has also been considered and is enclosed.

NEW MATTER

Claims 29-31 and 51-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

On page 44, lines 14-17, of the instant disclosure as filed a statistical program is cited to identify groups of attributes as representing a particular relationship but is not described as being generically performing one or more statistical operations without further limitation as set forth in newly added claims 29-31. This broadening of statistical operation practice over the above disclosure as filed is NEW MATTER. This broadened statistical practice is also set forth in claims 66—68.

In claim 51, line 2, a user with a tissue microarray is provided. It is noted that user access to microarray data for a variety of purposes is disclosed as filed, but consideration of the entire disclosure as filed has not revealed the providing of a user "with" a tissue microarray indicative of some particular providing as now set forth in the claims. This providing practice therefore is NEW MATTER.

VAGUENESS AND INDEFINITENESS

Claims 6-46 and 51-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6, line 4, the phrase "the network" is indicative of some previously cited network in the claim. Due to a lack of a previously cited network said phrase lacks clear antecedent basis as to what is meant thereby. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 6 also contain this unclarity due to their dependence.

In claim 6, line 2, the phrase "specimen-linked" is set forth which causes the claim to be vague and indefinite as to what the specimen is linked to due to a lack of linkage metes and bounds in the claim. For example, is each microarray in the claim linked to a specimen? Is the database linked to a specimen? Clarification via clearer claim wording is requested as to what specimen linkage is meant. Claims which depend directly or indirectly from claim 6 also contain this unclarity due to their dependence.

PRIOR ART REJECTION(S)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-17, 19-28, 32, 39-43, 46, 51-65, and 69-74 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kallioniemi et al. (WO 99/44062).

Kallioniemi et al. discloses the practice of tissue arrays in the abstract. The arrays of said abstract are reasonably interpreted as microarrays as instantly claimed because the microarray practice described in the instant specification lacks any limitation as to array size or density of tissue samples thereon which limits such interpretation other than that multiple tissues samples are deposited on such microarrays as is also set forth in said reference. EXAMPLE 1, however, does specifically cite a microarray as noted below. The arrays of the reference are identified by an identifier as to the type or source of tissue samples thereon, such as set forth in various examples of the arrays of the reference. EXAMPLE 1 is illustrative of an array identified as a breast cancer tumor tissue microarray starting on page 23 of the reference. A user interface for accessing desired array information including coordinates of samples on arrays (see specifically page 22, line 5, as in instant claims 7-15), which are set forth therein in databases, including a network connection is set forth on page 20, line 11, through page 23, line 25, as well as including output devices such as a display etc. Figures 25-27 depict image representations of tissue samples on microarrays as required in instant claims 11 and 12. Gene expression related to tumors

(cancer) is analyzed in EXAMPLE 4 on page 25 of the reference as also required in instant claims 16 and 17. Relationship searching for tumor marker profiles, for example, is cited on page 23, lines 15-25, as also required as an example embodiment of the instant claims 19-22. Other computers as a user as required in instant claim 23 is disclosed in the reference on page 20, lines 18-22. A hand held device which inherently has a wireless aspect to its operation is also cited on said page 20, line 17, as required in instant claim 24. Remote communications as set forth on page 20, lines 20-22, are well known to require a server as required in instant claim 25. The chemotherapy as set forth in the reference on page 24, line 1, describes drug exposure of tissue samples relating to efficacy as required in instant claim 32. These disclosures anticipate the above listed instant claims.

CITATIONS OF INTEREST

Foran et al. (PG Pub : 2003/0147552 A1) and Foran et al. (PG Pub: 2003/0118222 A1) are cited as of interest as describing tissue microarray information subject matter.

INFORMALITIES

The disclosure is objected to because of the following informalities:

In the specification on page 31, lines 7 and 26, blanks are present that must be amended to fill them in.

Appropriate correction is required.

No claim is allowed.

Art Unit: 1631

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

April 30, 2004

Ardin H. Marschel 4/30/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER